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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,132	05/02/2007	Kwang Do Choi	2511.0030000JUK/DLL	9220
26111 7590 10/04/2007 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER DAVIS, BRIAN J	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 10/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,132

Applicant(s)

CHOI ET AL.

Examiner

Brian J. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☒ Claim(s) 4, 5 and 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION***Claim Objections***

Claims 4, 5 and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The method of claim 4, or the composition of claim 5, do not further limit the *compounds* of claim 1. Likewise, the method of claim 7 does not further limit the *composition* of claim 5.

Claim Rejections - 35 USC § 112, FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions containing compounds of Formula 1 and their method of use in the treatment of obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy, does not reasonably provide enablement for *preventing* any of the above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With regard to rejections under 35 USC 112, first paragraph, the following factors are considered (*In re Wands* 8 USPQ 2d 1400, 1404 (CAFC 1988)): a) Breadth of claims; b) Nature of invention; c) State of the prior art; d) Level of ordinary skill in the art; e) Level of predictability in the art; f) Amount of direction and guidance provided by the inventor; g) Working examples and; h) Level of experimentation needed to make or use the invention based on the content of the disclosure.

a) The claims are quite broad: A pharmaceutical composition (claims 5 and 6) and a method (claim 7) for the treatment or prevention of obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy.

b,c) The nature of the invention is determined in part by the state of the prior art.

Even a cursory perusal of the teachings of the medicinal arts reveals that they have not advanced to the point where complex conditions such as obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy can be said to be preventable. The art, in general, teaches, instead, that what can be prevented with regard to such disorders are their associated symptoms, for example, seizure in the case of epilepsy.

d) The level of skill in the art is considered to be relatively high.

e) The level of predictability in the art is considered to be relatively low.

The basis of all modern medicine and biology is, of course, chemistry. Yet even under the best of circumstances, and several hundred years after Lavoisier

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laid the foundations of its modern practice, chemistry remains an experimental science. Neither the medicinal/biological arts nor the chemical arts upon which they are based have advanced to the point where certainty has replaced the need for clinical and/or laboratory experimentation.

f,g) The amount of direction provided by the inventor is considered to be determined by the specification and the working examples. Applicant's data do not demonstrate that the instant compounds prevent obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy.

h) Regardless of the amount of experimentation involved, applicant's claims to the prevention of the above disorders are not believable in light of the present understanding in the contemporary medicinal arts. It is settled case law that allegations of utility that are not believable in light of the contemporary knowledge in the art must be substantiated by acceptable evidence or stricken from the specification. In re Ferns, 163 USPQ 609 (CCPA 1969; Ex Parte Moore, 128, USPQ 8 (BPAI 1960); In re Hozumi, 226, USPQ 353 (Comr. Dec. 1985); MPEP 706.03(n) and 706.03(z).

Claim Rejections - 35 USC § 112, SECOND PARAGRAPH

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. The exact meaning of the term "related disorders" is unclear because it is undefined.

Allowable Subject Matter

Claims 1-3 are allowed. The following is a statement of reasons for the indication of allowable subject matter:

The closest prior art appears to be WO 2004096202 (CAPLUS abstract) which teaches structurally related salts of sibutramine e.g. RN=790240-88-9. The cited prior art neither teaches nor suggests the instant salts, however. Nor would it have been obvious to one of ordinary skill in the art at the time of the invention to modify the salts of the prior art in order to arrive at those of the instant invention. There is no motivation to do so.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: WO 2001051453 and CN 1274714 (both as CAPLUS abstracts) are cited to show related salts.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 **BRIAN DAVIS**
PRIMARY EXAMINER
Brian J. Davis
September 28, 2007